

REMARKS

The Office Action of March 8, 2004 has been received and reviewed. Claims 1, 2, 4, 6, 7, 10-16, 18, 20-24 and 43-49 are currently pending in the application. Claims 1, 2, 4, 6, 7, 10-16, 18, 20-24 and 43-49 stand rejected. Claims 1 and 7 have been amended as set forth herein. All amendments are made without prejudice or disclaimer. Reconsideration is respectfully requested.

Specification

The amendment filed December 21, 2004 was objected to for assertedly introducing new matter into the disclosure. (*See*, Office Action of March 8, 2004, hereinafter referred to as “Office Action,” at page 2). Specifically, it was thought that “[m]ere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. § 112, first paragraph.” (*Id.*, at page 3). However, the present specification states at page 46, lines 8-15 that “[a] DNA fragment . . . can be used as a probe . . . according to the hybridization method described by Sambrook et al. . . . NY.” Thus, it is evident that applicants intended to incorporate the hybridization method of Sambrook et al. Applicants again assert that this amendment satisfies the requirements set forth in *In re Hawkins*. *See, In re Hawkins*, 179 U.S.P.Q. 157 (CCPA 1973).

Furthermore, in the decision of *In re Howarth*, whose facts present a more extreme scenario than those of the present application, it was stated that even, “when no guide at all has been given, as here, an applicant must show that anyone skilled in the art would have actually

possessed the requisite knowledge (*In re Lange*, 644 F.2d 856, 863, 209 USPQ 288, 294 (CCPA 1981)) or would reasonably be expected to check the source which the applicant relies upon to complete his disclosure and would be able to locate the information with no more than reasonable diligence.” *In re Howarth*, 210 USPQ 689, 692-693 (CCPA 1981), *see also, In re Voss*, 194 USPQ 267 (CCPA 1977), stating that “[r]eference is made to United States Patent No. 2,920,971, granted to S. D. Stookey, for a general discussion of glass-ceramic materials and their production” and finding this general discussion sufficient to incorporate the patent by reference. One of ordinary skill in the art of molecular genetics would be familiar with the techniques and conditions contained in the amendment and would likely have a copy of Sambrook et al. at hand and would easily check the reference to locate the protocols contained therein.

Furthermore, applicants are not required to include in their specification every detail of information already known in the art. (*See, M.P.E.P. §2106.C*). As stated in the M.P.E.P. at § 2106.C, “[c]laims and disclosures are not to be evaluated in a vacuum. If elements of an invention are well known in the art, the applicant does not have to provide a disclosure that describes those elements.” Well known text books like the Sambrook, et al. reference, which is published in the English language, are not required to be provided verbatim in any disclosure especially when they are readily available to a person of ordinary skill in the art. Such textbooks are readily available to persons of ordinary skill in the art of molecular genetics and nothing more than reasonable diligence would be required to find the appropriate conditions utilized in the hybridization and wash protocols.

Reconsideration and withdrawal of the objection to the amendment to the specification is requested.

Objections under 37 C.F.R. § 1.75(c)

Claims 10-14 were objected to under 37 C.F.R. § 1.75(c) for being in improper form. Dependent claim 7 has been amended to depend only from claim 1, thus mooting the objection as to claims 10-14. Additionally, claim 1 was amended to improve the form thereof.

Reconsideration and withdrawal of the objection to claims 10-14 are respectfully requested.

Rejections Under 35 U.S.C. § 112, First Paragraph

Written Description/New Matter

Claims 48 and 49 stand rejected under 35 U.S.C. § 112, first paragraph, for assertedly failing to comply with the written description requirement. (*See*, Office Action, at page 3). Specifically, it was asserted that the specification, as originally filed, “does not describe hybridization wash conditions of 0.2X SSC, 0.1% (w/v) SDS at 68°C.” (*Id.*). Applicants traverse the rejections as set forth herein.

Applicants assert the aforementioned arguments recited in reply to the objection to the specification under 35 U.S.C. § 132, above, beginning at page 15, in response to this written description/new matter rejection. Applicants assert that Sambrook et al. was properly incorporated by reference in the specification and that this reference includes the hybridization wash conditions recited by claims 48 and 49.

Reconsideration and withdrawal of the written description/new matter rejection of claims 48 and 49 are respectfully requested.

Written Description

Claims 1, 2, 4, 6, 7, 10-16, 18, 20-24 and 43-49 are rejected under 35 U.S.C. § 112, first paragraph, for assertedly failing to comply with the written description requirement. (*Id.*, at page 4). Applicants traverse the rejections as set forth herein.

Specifically, it was thought that “the claims do not recite complete hybridization wash conditions,” and that the claims “still do not mention the temperature of the wash.” However, a person of ordinary skill in the art understands what is meant by stringent hybridization conditions based on the state of the art. Furthermore, an exact, verbatim description is not necessary to comply with the written description requirement. *See, Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991); *see also, Eiselstein v Frank*, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995) (with respect to “the ‘written description’ requirement with respect to later-filed claims, the prior application need not describe the claimed subject matter in exactly the same terms as used in the claims”; citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116; *see also, In re Wertheim*, 541 F.2d 257, 265, 191 USPQ 90, 98 (CCPA 1976) (“[L]ack of literal support . . . is not enough . . . to support a rejection under Section 112.”). Furthermore, as mentioned above, “[c]laims and disclosures are not to be evaluated in a vacuum. If elements of an invention are well known in the art, the applicant does not have to provide a disclosure that describes those elements.” *See, M.P.E.P. § 2106.C.* Since the present specification does include a detailed hybridization protocol and since it would be considered a routine procedure within the state of the art at the time the present application was filed, one of ordinary skill in the art would know how to perform the wash without undue experimentation.

Finally, applicants reiterate previous arguments made in their Reply under 37 C.F.R. § 1.111 of July 16, 2003 because these arguments remain were not addressed by the Office. Specifically, applicants reassert that the Office's rejection based on the lack of wash condition temperature is technically incorrect, as supported by the reasoning reiterated below.

Washing is important when the original hybridization conditions are low stringency to remove unrelated, hybridized sequences. In contrast, when stringent conditions are required, such as the conditions claimed in the present application, the need for removal of unrelated, hybridized sequences does not arise. Thus, since the hybridization conditions were stringent, there are very little, if any, unrelated sequences to remove by washing, and the precise wash conditions are not critical to the success of the invention.

Applicants again challenge the assertion that the temperature of the wash (following stringent hybridization) allows hybridization of unrelated sequences. This challenge is based on the reasoning above. Thus, applicants request that the Office produce evidence to support their assertion. If the Office maintains this rejection on these grounds, then the Office must provide an affidavit or declaration setting forth specific factual statements and explanations to support such an assertion as required by 37 C.F.R. §1.104(d)(2).

The new matter rejection of claims 48 and 49 were addressed above, in the section of this reply addressing the objection to the specification under 35 U.S.C. § 132. (*See, above, at page 15*).

Reconsideration and withdrawal of the written description rejection of claims 1, 2, 4, 6, 7, 10-16, 18, 20-24 and 43-49 are respectfully requested.

Enablement

Claims 1, 2, 4, 6, 7, 10-16, 18, 20-24 and 43-49 stand rejected under 35 U.S.C. § 112, first paragraph, for assertedly failing to comply with the enablement requirement. (See, Office Action, at page 5). Applicants traverse the enablement rejections as set forth herein.

Specifically, it was thought that “methods for gene targeting by homologous recombination were not known in the art at the time of filing for plant species other than *Chlamydomonas*.” (*Id.* at page 6). In contrast, as found in the publication of Hanin et al., Gene Targeting in *Arabidopsis*, *The Plant Journal*, 28(6):671-677, 2001 (Exhibit 1), there were several publications disclosing homologous recombination in plants dating back to the early 1990’s. (See, *Id.* at page 671, Introduction section). Furthermore, the technique of homologous recombination was performed in plants using *Agrobacterium tumefaciens* a decade or more before any of these references were published. The specification, starting at about page 10, line 23, describes in detail how *A. tumefaciens* is used to transform plant cells. Based on this disclosure, one of ordinary skill in the art would conclude that applicants were in possession of the invention.

Furthermore, applicants’ invention does not recite a requirement that homologous recombination be “gene targeted.” Transformation of the target plant is performed with the aid of *A. tumefaciens*. No reference is made to the transformation event requiring insertion of the gene into a specific location of the plant genome. All that is required is that resistance be imparted through introduction of a gene into the target plant genome, at any location within the target plant genome. (See, Claim 1).

Reconsideration and withdrawal of the enablement rejection of claims 1, 2, 4, 6, 7, 10-16, 18, 20-24 and 43-49 are respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, applicants believe the claims define patentable subject matter and a notice of allowance is requested. If any questions remain after consideration of the foregoing, the Office is invited to contact the applicants' attorney at the address or telephone number given herein.

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Respectfully submitted,

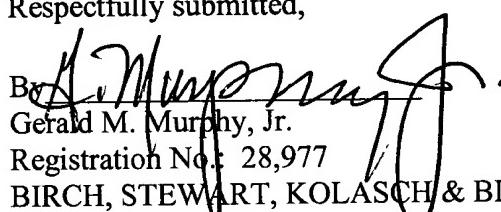

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Exhibit 1 – Hanin et al., The Plant Journal (2001), 28(6), 671-677


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